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March 8, 2001

Kate-Louise Gottfried, J.D., M.S.P.H.

Executive Director, Office for Human Research Protections
Office of Public Health and Science, OS
6100 Executive Boulevard, Room 3B01 (MSC-7507)
Rockville, MD 20892-7507

Re: Financial Relationships in Clinical Research: Issues for Institutions, Clinical Investigators, and IRBs to Consider when Dealing with Issues of Financial Interests and Human Subjects Protection

Dear Ms. Gottfried:

We would like to offer our comments on the draft interim guidance which is entitled "Financial Relationships in Clinical Research: Issues for Institutions, Clinical Investigators, and IRBs to Consider when Dealing with Issues of Financial Interests and Human Subjects Protection" (referred to in this letter as Guidance). Our association, the Federation of American Societies for Experimental Biology (FASEB) is comprised of 21 societies with more than 60,000 members, making it the largest coalition of biomedical research associations in the United States. The mission of FASEB is to enhance the ability of biomedical and life scientists to improve, through their research, quality of life for all people.

FASEB agrees with the concerns submitted to your office by the Association of American Universities (AAU), the Council on Government Relations (COGR), the National Association of State Universities and Land-Grant Colleges (NASULGC), and the Applied Research Ethics National Association (ARENA). We concur that the Guidance is overly prescriptive and is premature, given that many of these issues need more careful discussion before any regulations can be implemented.

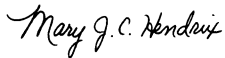
While we firmly believe that policy decisions must be made concerning financial relationships and human research protections, we feel that the Guidance fails to adequately address many important issues. The Guidance gives little attention to non-academic institutions such as Contract Research Organizations, where many clinical trials are conducted. Furthermore, the Guidance implies a substantial increase in the role of IRBs in the analysis and management of financial conflicts, which are now usually the responsibility of Conflict of Interest Committees. We believe that this issue requires considerably more discussion and consensus before imposing these additional burdens upon IRBs. Institutional regulation of financial conflicts of interest and the relationship between IRBs and university conflict of interest procedures are currently being examined by many institutions, as well as by "blue ribbon" committees of both AAU and the Association of American Medical Colleges. We feel that the Guidance has failed to take into consideration these ongoing initiatives.

March 8, 2001

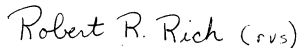
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We support the recommendation of AAU, COGR, NASULGC, and ARENA that the Office of Human Research Protections withdraw the current guidelines as they were issued without sufficient substantive debate.

Respectfully yours on behalf of the FASEB membership,

A handwritten signature in cursive script, reading "Mary J.C. Hendrix".

Mary J.C. Hendrix, Ph.D.
FASEB President

A handwritten signature in cursive script, reading "Robert R. Rich (rvs)".

Robert R. Rich, M.D.
FASEB President-Elect